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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/772,927 | 02/04/2004 | Kari Alitalo | 28967/39140B | 7264 |

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| EXAMINER | |
|---|---|
| BUNNER, BRIDGET E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1647 | |

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/772,927 | ALITALO ET AL. | |
| | Examiner | Art Unit | |
| | Bridget E. Bunner | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *95-190* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *95-190* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application, Amendments and/or Claims*

The amendments of 01 July 2004 and 20 June 2005 have been entered in full. Claims 1-94 are cancelled. Claims 95-190 are added.

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 96-105, 109-112, drawn to a method of stimulating stem cell recruitment proliferation or differentiation comprising identifying a subject in need thereof and administering a VEGF-B polypeptide, classified in class 424, subclass 198.1.

II. Claims 96-103, 106-108, and 112, drawn to a method of stimulating stem cell recruitment proliferation or differentiation comprising identifying a subject in need thereof and administering a VEGF-B polynucleotide, classified in class 514, subclass 44.

III. Claims 114-125, 129-132, drawn to a method of stimulating stem cell proliferation or differentiation comprising obtaining a biological sample from a subject and contacting the stem cells with a VEGF-B polypeptide, classified in class 435, subclass 377.

IV. Claims 114-123, 126-128, and 132 , drawn to a method of stimulating stem cell proliferation or differentiation comprising obtaining a biological sample from a subject and contacting the stem cells with a VEGF-B polynucleotide, classified in class 435, subclass 6.

V. Claims 134-138, and 142-147, drawn to a method of stimulating stem cell recruitment, proliferation, or differentiation comprising identifying a subject in need thereof and administering to the subject a composition comprising a PDGF polypeptide, classified in class 424, subclass 198.1.

VI. Claims 134-135, 139-141, and 146-147, drawn to a method of stimulating stem cell recruitment, proliferation, or differentiation comprising identifying a subject in need thereof and administering to the subject a composition comprising a PDGF polynucleotide, classified in class 514, subclass 44.

VII. Claims 149-161, 165-183, and 186-190, drawn to a method of stimulating stem cell proliferation or differentiation comprising obtaining a biological sample from

a subject and contacting the stem cells with a composition comprising a PDGF polypeptide, classified in class 435, subclass 377.

VIII. Claims 149-160, 162-164, 167-179, and 186-190, drawn to a method of stimulating stem cell proliferation or differentiation comprising obtaining a biological sample from a subject and contacting the stem cells with a composition comprising a PDGF polynucleotide, classified in class 435, subclass 6.

IX. Claims 184-185, drawn to a method of stimulating stem cell proliferation or differentiation comprising obtaining a biological sample from a subject, contacting a first aliquot of stem cells with a first polypeptide and contacting a second aliquot of stem cells with a second growth factor polypeptide, classified in class 435, subclass 7.1.

X. Claims 184-185, drawn to a method of stimulating stem cell proliferation or differentiation comprising obtaining a biological sample from a subject, contacting a first aliquot of stem cells with a first polynucleotide and contacting a second aliquot of stem cells with a second growth factor polynucleotide, classified in class 435, subclass 6.

2. Claim 95 link(s) inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 95.

3. Claim 113 link(s) inventions III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 113.

4. Claim 133 link(s) inventions V and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 133.

5. Claim 148 link(s) inventions VII and VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 148.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined

for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

a. Inventions I-X are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Groups I-X are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention I requires search and consideration of identifying a subject in need of stem cell recruitment, proliferation, or differentiation and administration a VEGF-B polypeptide, which is not required by the other inventions. Invention II requires search and consideration of identifying a subject in need of stem cell recruitment, proliferation, or differentiation and administration a VEGF-B polynucleotide,

which is not required by the other inventions. Invention III requires search and consideration of obtaining a biological sample from a subject and contacting the stem cells with a VEGF-B polypeptide, which is not required by the other inventions. Invention IV requires search and consideration of obtaining a biological sample from a subject and contacting the stem cells with a VEGF-B polynucleotide, which is not required by the other inventions. Invention V requires search and consideration of identifying a subject in need of stem cell recruitment, proliferation, or differentiation and administration a PDGF polypeptide, which is not required by the other inventions. Invention VI requires search and consideration of identifying a subject in need of stem cell recruitment, proliferation, or differentiation and administration a PDGF polynucleotide, which is not required by the other inventions. Invention VII requires search and consideration of obtaining a biological sample from a subject and contacting the stem cells with a composition comprising a PDGF polypeptide, which is not required by the other inventions. Invention VIII requires search and consideration of obtaining a biological sample from a subject and contacting the stem cells with a composition comprising a PDGF polynucleotide, which is not required by the other inventions. Invention IX requires search and consideration of obtaining a biological sample from a subject, contacting a first aliquot of stem cells with a first polypeptide and contacting a second aliquot of stem cells with a second growth factor polypeptide, which is not required by the other inventions. Invention X requires search and consideration of obtaining a biological sample from a subject, contacting a first aliquot of stem cells with a first polynucleotide and contacting a second aliquot of stem cells with a second growth factor polynucleotide, which is not required by the other inventions.

Furthermore, the distinct steps and products require separate, distinct, and non-coextensive searches. As such, it would be burdensome to search the inventions of Groups I-X together.

6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification and require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species: the further administration of an agent selected from the group:

a. G-CSF

b. M-CSF

c. GM-CSF

d. IL-3

e. SCF

f. VEGF

g. VEGF-C

h. VEGF-D

i. PDGF-A

j. PDGF-B

k. PDGF-C

l. PDGF-D

m. P1GF

n. a nucleotide sequence encoding one of (a) through (m)

The species are independent or distinct because each of the agents listed as (a)-(n) have different structural and functional characteristics. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for administration of G-CSF may not result in relevant art with respect to administration of polynucleotides encoding P1GF.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 95, 133, 148 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. This application contains claims directed to the following patentably distinct species: a method of administering any PDGF product or further contacting cells with any PDGF product wherein the PDGF is:

o. PDGF-A

p. PDGF-B

q. PDGF-C

r. PDGF-D

The species are independent or distinct because each of the PDGF products listed as (o)-(r) have different structural and functional characteristics. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for administration or cell contact with PDGF-A may not result in relevant art with respect to administration or contact with PDGF-D.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 133 and 148 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. This application contains claims directed to the following patentably distinct species: a method of contacting stem cells with a PDGF composition wherein the PDGF product is:

s. PDGF-C

t. PDGF-D

The species are independent or distinct because each of the PDGF products listed as (s)-(t) have different structural and functional characteristics. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for contact of stem cells with PDGF-C may not result in relevant art with respect to contact of stem cells with PDGF-D.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 148 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. This application contains claims directed to the following patentably distinct species: contacting a first aliquot of stem cells with a growth factor product selected from a:

u. VEGF-B product

v. PDGF-C product

The species are independent or distinct because each of growth factor products listed as (u)-(v) have different structural and functional characteristics. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for cell contact with VEGF-B may not result in relevant art with respect to cell contact with PDGF-C.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 184 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. This application contains claims directed to the following patentably distinct species: contacting a second aliquot of stem cells with a second growth factor wherein the second growth factor is:

w. VEGF-A

x. VEGF-B

y. VEGF-C

z. VEGF-D

aa. PDGF-A

bb. PDGF-B

cc. PDGF-C

dd. PIGF

The species are independent or distinct because each of the growth factors listed as (x)-(dd) have different structural and functional characteristics. The species are independent or distinct because each requires separate, non-coextensive searches. For example, a technical literature search for cell contact with VEGF-A may not result in relevant art with respect to cell contact with P1GF.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 184 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**If Applicant selects Invention I-VIII, one species from the additional agent group ((a)-(n)) must also be chosen to be considered fully responsive.**

**If Applicant selects Invention V-VIII, one species from the PDGF product group ((o)-(r)) must also be chosen to be considered fully responsive.**

**If Applicant selects Invention VII or VIII, one species from the PDGF group of ((s)-(t)) must also be chosen to be considered fully responsive.**

**If Applicant selects Invention IX or X, one species from the first growth factor group ((u)-(v)) and one species from the second growth factor group ((w)-(dd)) must also be chosen to be considered fully responsive.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
21 August 2006

Bridget E. Bunner
BRIDGET BUNNER
PATENT EXAMINER